The applicants erroneously filed an additional preliminary amendment on 31 May 2001 which appears to have been properly ignored by the PTO. The claims under examination during the first office action were claims 8-20 as recited in the preliminary amendment of 24 January 2001.

Claim 8 has been amended to incorporate the limitations of previous claims 12 and 15. Claim 20 has been amended to use the preparation of claim 8. New claims 21-23 have been added. Support for these claims can be found e.g. on pages 11-12. It is believed that no new matter has been added.

Priority

Please note that the published PCT (i.e. WO 00/07557 – front page was submitted with papers filed with application) denotes a claim for priority of 1 August 1998 based on DE 198 34 814.2, i.e. there is no evidence that the applicants' claim for priority was denied by the International Bureau (see MPEP 201.13(b) and PCT Rule 17.1 (a)-(c)) as such it is unclear what is the basis for asserting that the applicants' have not submitted a certified copy of the foreign priority document (Applicants' will double check to see that it has indeed been submitted).

Information Disclosure Statement

Please note that an information disclosure statement was filed on 31 May 2001 (a copy of the IDS without copies of the references and the stamped postcard is being submitted with this communication). The applicants respectfully request consideration of these references and a signed copy of the Form 1449 with the examiner's next communication.

Specification

An objection was made alleging the introduction of new matter into the disclosure (actually claims 16 and 17). The examiner is directed towards page 10, lines 18-21 which reads "It is also advantageous to administer the active ingredients according to the invention in encapsulated form, e.g. as cellulose encapsulations, in gelatin, wax matrices or liposomally encapsulated."

35 U.S.C. § 112, second paragraph rejection

Claims 8, 9, 13, 15 and 17-20 were rejected by the examiner as being indefinite for various reasons for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. (Lower case Roman numerals used below correspond to those used in the first Office Action):

(i) The term "derivative" is not used alone but in the phrase "derivatives of bile acids". The examiner is reminded that MPEP 2173.04 states that "Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.").

Moreover, "During patent examination, the pending claims must be given the broadest reasonable interpretation ***consistent with the specification***. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). See also MPEP § 2111 - § 2111.01.

(ii) Although it is believed that one of ordinary skill in the art would be able to determine the scope of claim 9, in rder to expedite prosecution the above amendment was presented. Support for the various modifications can be found for example on page 9, lines 25-26, page 10, 3rd to last line thru page 12, line 6.

(iii) The examiner is again referred back to page 10, lines 18-21 of the specification (and any common reference with regard to cosmetic or pharmaceutical preparation such as *Remington's Pharmaceutical Sciences*, *ICI Dictionary and Handbook*, *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, etc.). Encapsulation form refers to what is being done to the active ingredient; claim 17 provides a further limitation on the agents which perform the encapsulation.

(iv) When a term is not defined in the specification, the term reverts to its plain meaning (MPEP 2111.01).

The examiner also appears to imply that use of relative terms are by definition vague and indefinite. However, this would be incorrect (see MPEP 2173.01 – Claim Terminology – "Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which prosecution is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought."

In addition, the applicants have disclosed an example means by which barrier function can be quantified (see page 3, lines 13-14 – "The barrier effect of the skin can be quantified via the determination of the transepidermal water loss (TEWL).")

(v) The description refers repeatedly to the term "barrier function" (e.g. page 1, lines 5-10 – "...the barrier function, which prevents the skin from drying out...This barrier function is effected by the epidermis which, as the outermost layer, forms the actual protective sheath against the environment.")

The applicants are permitted to be their own lexicographer and their use of the term "barrier function" is not at odds with how one of ordinary skill in the art in the cosmetic and dermatological arts (which presumably would include an understanding of the integumentary system) would view the term.

(vi) The examiner appears to believe that these two limitations are mutually exclusive. This is incorrect. This is an additional limitation upon the type of encapsulation form (i.e. an encapsulation form that is also a solution form, e.g a liposomal encapsulation). – (As another means of visualization, the active ingredient of a CONTAC cold capsule, i.e. the pellets, are encapsulated by a plastic capsule and as such is in encapsulated form and the encapsulated form is that of a plastic capsule.)

(vii) Claim 15 has been amended to clarify that the salts and derivatives are salts and derivatives of bile acids as stated in claim 8.

35 U.S.C. § 102(b) and 102(e) rejections

Given the amendments made to the claims, it is believed that the examiner's previous rejections have

been rendered moot.

In the interest of compact prosecution, the examiner is reminded that MPEP 706.02 (Choices of Prior Art) states that: "Prior art rejections should ordinarily be confined strictly to the best available art. Exceptions may properly be made, for example, where:

(A) the propriety of a 35 U.S.C. 102 or 103 rejection depends on a particular interpretation of a claim;
(B) a claim is met only in terms by a reference which does not disclose the inventive concepts involved; or
(C) the most pertinent reference seems likely to be antedated by a 37 CFR 1.131 affadavit or declaration.

Such rejections should be backed up by the best other art rejection available. Merely cumulative rejections, i.e. ***those which would clearly fall if the primary rejection were not sustained should be avoided.***" While the examiner has the discretion to draft her office action as she sees fit (and noting that the applicants' do not necessarily agree with the validity of any of the rejections), it would appear that the time to write the previous office action could have been greatly reduced with a more judicious use of references (By way of example, JP 03058918 was used twice to reject the same claims, 8-13, 15 and 18-20).

Closing

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (5 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: **18 December 2002**

By: _____
Vilma I. Fernandez

COPY OF ALL PENDING CLAIMS AND SHOWING AMENDMENTS MADE

8. A cosmetic and/or dermatological preparation comprising an active ingredient ***in an amount of about 0.01% to about 0.5% by weight, based on the total weight of the preparation, wherein the active ingredient is a bile acid salt wherein the salt is selected from the group consisting of alkali metal and alkaline earth metal salts, salts of mono- or divalent cations of elements from the transition groups, salts of mono- or divalent cations of elements from the lanthanides, salts of mono- or divalent cations of elements from the actinides, salts of ammonium ($-NH_3$), and salts of basic amino acids, or a bile acid derivative wherein the derivatization is selected from the group consisting of alkanoammonium having 2 to 9 carbon atoms in total, alkyl- and alkenylammonium having 1 to 22 carbon atoms in total, and pyridine substituted by an alkyl or alkenyl group which has 1 to 18 carbon atoms*** **[selected from the group consisting of bile acids, salts of bile acids, derivatives of bile acids, and mixtures thereof]**.

9. The preparation according to Claim 8, further comprising cosmetic or dermatological auxiliaries, ***antioxidants, UV-A or UV-B filter substances, inorganic pigments, antioxidants and mixtures thereof*** **[additives, and/or other active ingredients]**.

13. The preparation according to Claim 8, wherein the active ingredient is selected from the group consisting of deoxycholic acid, ursodeoxycholic acid, taurocholic acid and salts and derivatives thereof.

14. The preparation according to Claim 8, wherein the active ingredient is selected from the group consisting of esters of bile acids and ethers of bile acids.

16. The preparation according to Claim 8, wherein the preparation is in an encapsulated form.

17. The preparation according to Claim 16, wherein the encapsulated form is selected from the group consisting of collagen matrices, cellulose encapsulations, gelatin, wax matrices, and liposomal encapsulations.

18. The preparation according to Claim 16, wherein the preparation is in solution form.

19. A method for strengthening the barrier function of the skin that comprises applying the preparation according to Claim 8 to the skin.

20. A method for strengthening the barrier function of the skin that comprises applying a ***barrier strengthening effective amount of a*** preparation ***of claim 8*** **[comprising about 0.01% to about 0.5% by weight, based on the total weight of the preparation, of an active ingredient selected from the group consisting of deoxycholic acid, ursodeoxycholic acid, taurocholic acid, and salts and derivatives thereof]** to the skin.

21. The preparation of claim 8, further comprising antioxidants in an amount of 1-10% by weight, based on the total weight of the preparation.

22. The preparation of claim 21, wherein said antioxidants are vitamin E and/or derivatives thereof in an amount of 0.001 – 10% by weight, based on the total weight of the preparation.

23. The preparation of claim 22, wherein said vitamin E and/or derivatives thereof is tocopheryl acetate.

CASE # : Beiersdorf 704-HCL **SERIAL NO.: 09/744,506**
DATE MAILED: May 31, 2001 **DATE DUE:**

The stamp of the Patent Office hereon may be taken as acknowledgment of receipt, on the date stamped, of the following:

1) Transmittal Form
2) Preliminary Amendment
3) Information Disclosure Statement
   - Concise Statement of Relevance of Non-English References
4) PTO Form 1449
   - Copies of all 11 references listed